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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,185	06/01/2001	David M. Stern	0575/64080/JPW/SHS/ALB	2919

7590 09/14/2004

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,185

Applicant(s)

STERN ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,7-13 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,7-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/04/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/04/2004 has been entered. An action on the RCE follows.
2. Claims 1-3 and 7-18 are pending. Claims 1-2 and 14-15 are withdrawn. Therefore, claims 3, 7-13 and 16-18 are pending and are examined.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.
4. The Office Acknowledges the receipt of supplemental IDS of 06/04/2004.

Claim Rejections - 35 USC § 103, maintained

5. Rejection of claims 3 and 7-11 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) is maintained for reasons of record of the Office Action of 6/17/2003 and 02/20/2004. Applicant's arguments, filed 06/04/2004, with respect to rejection of claims 3 and 7-11 has been considered fully but is not persuasive. Applicant asserts that the invention is based on the surprising discovery that inhibiting the interaction of RAGE and either AGE or EN-RAGE is useful in treating inflammation as evidenced by the experimental data. However, Applicant fails to indicate which if any of the experimental data is the "surprising discovery" to support the assertion (see page 6 of the remarks). Applicants'

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position that prior to Applicants' discovery, there was no reasonable expectation that inhibiting the interaction of RAGE and either AGE or EN-RAGE would succeed in treating inflammation is not persuasive because as indicated previously, Ritthaler et al. (1995) clearly implicated RAGE/AGE interaction in inflammation related pathology. Specifically, Ritthaler et al. disclose that the interaction of AGE and RAGE may contribute to the development of vacular lesions and that examination of human atherosclerotic plaques or experimentally induced inflammatory lesions in response to local instillation of AGEs, showed prominent accumulation of cells strikingly positive for RAGE (see abstract and page 688, column 2), thus clearly implicating RAGE/AGE in inflammation related pathogenesis. Further, Morser et al. teaches that blocking agents inhibit or otherwise reduce the AGE/RAGE interaction (abstract). The reference also teaches that soluble human RAGE (sRAGE) and antibodies to RAGE that inhibit the ability of ligands (such as AGEs and amphoterin) to bind to RAGE, said sRAGE or antibodies are useful for treating disorders or symptoms which result from the association between RAGE and its ligands (column 6, lines 53-56 and column 11, lines 53-56). Morser et al. also disclose methods of treatment for pathological conditions involving RAGE by administering orally, intravenously, intraperitoneal or intramuscularly, liposome formulations an effective amount of the sRAGE polypeptide or anti-RAGE antibodies to a mammal including humans (column 19 line 5 to column 20 line 28). Further, it should be noted that, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

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F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus, one of ordinary skill in the art would have been motivated to adapt the method of treating inflammation by inhibiting the interaction of RAGE and its ligands by administering sRAGE or the anti-RAGE antibodies described in Morser et al. and because Ritthaler et al. have showed that RAGE and its ligands may play a role in inflammation. Therefore, rejection of claims 3 and 7-11 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) in view of Ritthaler et al. (1995) is maintained.

6. Rejection of claims 12, 13 and 16-18 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) and Ritthaler et al. (1995) in view of Baker et al. (U. S. Patent No: 5, 998, 408) is maintained for reasons of record of the Office Action of 6/17/2003 and 02/20/2004. Applicant's arguments, filed 06/04/2004, with respect to rejection of claims 12, 13 and 16-18 has been considered fully but is not persuasive. Applicant's arguments regarding the lack of obviousness with respect to Morser et al. (U. S. Patent No: 5, 864,018) and Ritthaler et al. (1995) has been addressed above in paragraph 5. Baker et al. discloses autoimmune disease and inflammation associated with it. In addition, it also teaches diseases which are often involved inflammation or inflammatory process. Applicant's arguments with respect to the surprising discovery underlying the claimed invention has also been addressed above. Therefore, rejection of claims 12, 13 and 16-18 under 35 U.S.C. 103(a) as being obvious over Morser et al. (U. S. Patent No: 5, 864,018) and Ritthaler et al. (1995) in view of Baker et al. (U. S. Patent No: 5, 998, 408) is maintained.

Double Patenting

7. Provisional rejection of claim 3-11 and 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 47, 50, 55-60, 62-65 and 67 of copending Application No. 09/167705 in view of Morser et al. (U. S. Patent No: 5, 864,018) and of Ritthaler et al. (1995) is maintained for reasons for reasons of record in the Office Action of 6/17/2003. Although, Applicant has indicated that that a terminal disclaimer will be filed, none has been filed yet, thus the rejection is maintained.

8. No claims are allowable.

Contact Information

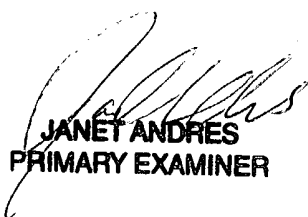
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS/09/04


JANET ANDRES
PRIMARY EXAMINER